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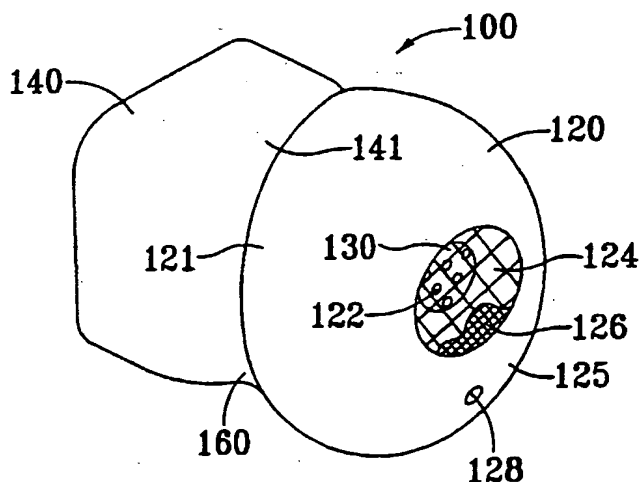
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(54) Title: CONFORMAL TIP FOR A HEARING AID



(57) Abstract: A conformal tip (100) for a hearing de-
vice comprises a circumferentially enlarged sealing por-
tion (120) proximate a distal end of the conformal tip. The
sealing portion (120) is configured to form a seal with a
wall of an ear canal. The shape of the conformal tip allows
effective acoustic sealing of the ear canal and reduction of
occlusion effects while maintaining a minimum amount
of contact with the ear canal wall. Preferably, the confor-
mal tip is formed from a compressible foam material.

WO 01/43500 A1

SPECIFICATION

CONFORMAL TIP FOR A HEARING AID

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FIELD OF THE INVENTION

The present invention pertains to hearing aids. More particularly, the present invention pertains to conformal tips for hearing aids.

BACKGROUND OF THE INVENTION

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The modern trend in the design and implementation of hearing devices is focusing to a large extent on reducing the physical size of the hearing device. Miniaturization of hearing device components is becoming increasingly feasible with rapid technological advances in the fields of power supplies, sound processing electronics and micro-mechanics. The demand for smaller and less conspicuous hearing devices continues to increase as a larger portion of our population ages and faces hearing loss. Those who face hearing loss also encounter the accompanying desire to avoid the stigma and self consciousness associated with this condition. As a result, smaller hearing devices which are cosmetically less visible are increasingly sought after.

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Hearing device technology has progressed rapidly in recent years. First generation hearing devices were primarily of the Behind-The-Ear (BTE) type, where an externally mounted device was connected by an acoustic tube to a molded shell placed within the ear. With the advancement of component miniaturization, modern hearing devices rarely use this Behind-The-Ear technique, focusing primarily on one of several forms of an In-The-Canal hearing device. Three main types of In-The-Canal hearing devices are routinely offered by audiologists and physicians. In-The-Ear (ITE) devices rest primarily in the concha of the ear and have the disadvantages of being fairly conspicuous to a bystander and relatively bulky to wear. Smaller In-The-Canal (ITC) devices fit partially in the concha and partially in the ear canal and are less visible but still leave a substantial portion of the hearing device exposed. Recently, Completely-In-The-Canal (CIC) hearing devices have come into greater use. As the name implicates, these devices fit deep within the ear canal and are essentially hidden from view from the outside.

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In addition to the obvious cosmetic advantages these types of in-the-canal devices provide, they also have several performance advantages that larger, externally

mounted devices do not offer. Placing the hearing device deep within the ear canal and proximate to the tympanic membrane (ear drum) improves the frequency response of the device, reduces distortion due to jaw extrusion, reduces occlusion effects and improves overall sound fidelity.

5 The shape and structure, or morphology, of the ear canal varies from person to person. However, certain characteristics are common to all individuals. When viewed in the transverse plane, the path of the ear canal is extremely irregular, having several sharp bends and curves. Also, the diameter of the ear canal usually becomes smaller toward its deeper regions and the cross section of the ear canal is usually not circular. It is these
10 inherent structural characteristic which create problems for the acoustic scientist and hearing device designer.

 For general discussion purposes, the ear canal can be broken into three main segments. The external and medial segments are both surrounded by a relatively soft cartilaginous tissue. The external segment is largely visible from the outside and
15 represents the largest cavity of the ear canal. The innermost segment of the ear canal, closest to the tympanic membrane, is surrounded by a denser bony material and is covered with only a thin layer of soft tissue. The bony material allows for little expansion to occur in this region compared with the cartilaginous regions of the external and medial segments of the ear canal. In addition to being surrounded by cartilage rather than bone, these areas
20 are covered with a substantially thicker tissue layer. As such, pressure exerted by an ITC hearing device on the inner bony region of the canal can lead to discomfort and/or pain to an individual, especially when a deep insertion technique is used and there is a large contact area between the hearing device and the ear canal.

 Since the morphology of the ear canal varies so greatly from person to person,
25 hearing aid manufacturers and audiologists frequently employ custom manufactured devices in order to precisely fit the dimensions of each user's ear canal. This may necessitate impressions of the user's ear canal to be taken. The resulting mold is then used to fabricate a rigid hearing device shell. This process is both expensive and time consuming and the resulting rigid device shell does not perform well during the
30 deformations of the ear canal that occur during normal jaw movement. In order to receive a properly fit hearing device, the user typically has to make several trips to the audiologist for reshaping and resizing. Even after the best possible fit is obtained, the rigid shell

rarely provides comfortable hearing enhancement at all times since it does not adapt to the changing shape of the ear canal..

Further, because the resulting hearing aid device shell is typically formed from a hard acrylic material, discomfort to the user is typical when worn for extended periods of time. The inability of the hard shell to conform to normal ear canal deformations can cause it to become easily dislodged from its proper position. Consequently, the quality of the hearing enhancement suffers. Due to the added manufacturing costs, it is desirable to utilize a hearing device that is at least partially formed from an off-the-shelf or pre-formed component readily available to the audiologist or physician.

While the performance of CIC hearing devices are generally superior to other larger and less sophisticated devices, several problems remain prevalent. Complications typically arise as a result of the small size of CIC hearing devices and the depth to which they are inserted into a user's ear canal.

For example, because a CIC hearing device preferably forms an essentially air tight acoustic seal between the tip of the hearing device and the walls of the ear canal, discomfort to a user is common. This seal prevents the equalization of pressure between the internal chamber formed between the tympanic membrane and the hearing device, and the ambient environment. Due to the sensitivity of the tympanic membrane, even small pressure differentials can cause severe discomfort. Further, due to their small size and positioning within the ear canal, CIC hearing devices can cause handling problems, making insertion and removal by a user difficult and cumbersome.

U.S. Patent No. 5,701,348, entitled "Articulated Hearing Device" ("the '348 patent"), discloses a multi-segment hearing device with several articulating and non-contiguous parts. The hearing device of the '348 patent includes a rigid receiver module with a surrounding acoustic seal. The acoustic seal of the '348 patent includes a rounded sheathing made from a singular piece of foam or silicone which compresses when inserted into the deep regions of an ear canal. The '348 patent also describes the use of this sealing mechanism as an anchor so that the remaining articulating components of the hearing device, which are not covered by the seal, can move freely in relation to each other and adjust to deformations of the ear canal.

While providing an anchor for the hearing device, the foam or silicone sheathing of the '348 patent does not account for the irregular size and shape of the ear canal. This may result in a poor acoustic seal. Further, this device may present comfort

problems during extended period of wear because there are still portions of the rigid hearing device that may contact the ear canal and a large area of the sheathing is in contact with the ear canal. The foam or silicone tip of the '348 patent is either inseparable from the receiver housing or requires additional hardware, such as a threaded connection, snap or a clip to attach it. The ability to effectively interchange and clean the sealing material is therefore compromised and will sometimes require the assistance of an audiologist or technician, particularly to users with poor dexterity. The device taught by the '348 patent is not conducive to use with a deeply inserted completely in the canal hearing device (CIC) seeking to minimize contact between the acoustic seal and the ear canal wall.

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SUMMARY OF THE INVENTION

A conformal tip constructed in accordance with the present invention solves the foregoing problems by providing a conformal tip for a hearing aid that is shaped to allow effective acoustic sealing of the ear canal and reduction of acoustic feedback and occlusion effects while maintaining a minimum amount of contact with the ear canal wall.

In a first aspect of the present invention, a conformal tip comprises a circumferentially enlarged sealing portion proximate a distal end of the conformal tip. The sealing portion is configured to form a seal with a wall of an ear canal.

In another aspect of the invention, a conformal tip comprises a sealing portion and a retention portion. The sealing portion and the retention portion are connected to define a narrowed region of the conformal tip. Preferably, the conformal tip is formed from a compressible self-recovering foam material.

In another aspect of the present invention, the conformal tip further comprises a vent aperture on a distal end of the sealing portion. The vent aperture is preferably in communication with a channel that extends from the vent aperture to a proximal surface of the retention portion. The vent aperture can alternately be adapted to align with a similar aperture on a hearing device receiver module.

Other and further aspects and advantages of the invention will become apparent hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings illustrate both the design and utility of the preferred embodiments of the present invention, in which similar elements in different embodiments are referred to by the same reference numbers for purposes of ease in illustration of the invention,

5 wherein:

Fig. 1 is a front perspective view of a conformal tip constructed in accordance with the present invention;

Fig. 2 is a rear perspective view of a conformal tip constructed in accordance with the present invention

10 Fig. 3 is a front elevation view of a conformal tip constructed in accordance with the present invention;

Fig. 4 is a rear elevation view of a conformal tip constructed in accordance with the present invention;

15 Fig. 5 is a right side elevation view of a conformal tip constructed in accordance with the present invention;

Fig. 6 is a top plan view of a conformal tip constructed in accordance with the present invention

20 Fig. 7 is an exploded perspective view of a completely in-the-canal (CIC) hearing device utilizing a preferred embodiment of a conformal tip constructed in accordance with the present invention; and

Fig. 8 is a perspective view of a completely in-the-canal hearing device engaged with a conformal tip constructed in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A conformational tip constructed in accordance with the present invention can be, and is preferably used with, a completely in-the-canal (CIC) hearing device. CIC hearing devices are single module devices with all operating electronics and mechanics contained within a single housing. U.S. Patent Application Nos. [not yet assigned], filed on the same day as the present application, discloses and teaches several examples of a preferred CIC hearing device, the details of which are hereby fully incorporated by reference into the present application. Alternately, a conformational tip constructed in accordance with the present invention can be adapted for use with an ITC hearing device. U.S. Patent Application Nos. 09/161,344, filed on September 25, 1998, entitled "Conformational In-The-Canal Hearing Device", and 09/231,282, filed on January 15, 1999, entitled "Conformational Tip for a Hearing Aid", disclose and teach preferred examples of such an ITC hearing device, the details of which are hereby fully incorporated by reference into the present application.

Figs. 1-6 show a preferred embodiment of a conformational tip 100, constructed in accordance with the present invention. The conformational tip 100 includes a sealing portion 120 that has a generally bulbous shape, and a retention portion 140. A proximal end 121 of the sealing portion 120 and a distal end 141 of the retention portion 140 are tapered toward each other and are joined so that a narrowed region 160 is formed between the sealing portion 120 and the retention portion 140. The sealing portion 120 has a lateral cross section (See e.g. Fig. 3) that is preferably substantially oval. More particularly, the sealing portion 120 is shaped to substantially resemble the typical cross section of an ear canal. The sealing portion 120 defines an internal chamber 123 that also has a generally bulbous shape.

A cavity 124 is included on a distal end 125 of the sealing portion 120. The cavity 124 includes an innermost surface 130 which includes at least one aperture 122. Preferably a plurality of apertures 122 are included on the surface 130. The cavity 124 is enclosed by a membrane 126 mounted flush with the distal end 125 of the sealing portion 120. The membrane 126 is transparent to acoustic energy while also preventing cerumen, dirt and moisture, and other contaminants from entering the chamber 123 and potentially interfering with the operation of the hearing device. As such, the membrane 126 preferably includes a cerumen repellent coating.

Also located on the distal end 125 of the sealing portion 120 is a vent aperture 128 that extends from the distal end 125 of the sealing portion 120 into the chamber 123. The vent aperture 128 allows air exchange, and therefore pressure equalization, between the distal end 125 of the sealing portion 120, which is in close proximity to the tympanic membrane, and the outside environment. The vent aperture 128 is in communication with a channel 144 (Best seen in Fig. 2) that extends through the sealing portion 120 and the retention portion 140 and to a proximal surface 143 of the conformal tip 100, and to the outside environment. The sealing portion 120 has a longitudinal profile, both from its side (Best seen in Fig. 5), and from its top (Best seen in Fig. 6), that causes only a small contact area 132 of the sealing portion 120 to touch the wall of an ear canal when worn by a user. Alternately, when a receiver module is inserted into the conformal tip 100, the vent aperture 128 aligns with a similar vent aperture on the receiver module, allowing pressure equalization to occur directly through the receiver module rather than through the channel in the conformal tip. In such an embodiment, the channel is unnecessary.

The retention portion 140 is shaped to receive a CIC hearing device. As such, the retention portion 140 preferably has a generally rectangular lateral profile (Best seen in Fig. 4) and defines a generally rectangular chamber 142. At an innermost portion of the chamber 142 is a seat 146 that extends from the inside surface of the chamber 142. The seat 146 restricts the size of the chamber 142 and prevents a hearing device from being inserted beyond its surface.

Figs. 5 and 6 show a dashed line that indicates a wall 170 of an ear canal. The ear canal wall 170 is shown slightly tapered since it becomes more restricted at its deeper regions. The narrowed region 160 of the conformal tip 100 formed between the proximal end 121 of the sealing portion 120 and the distal end 141 of the retention portion 140 further emphasizes the reduced contact area 132 between the sealing portion 120 and the wall 170 of an ear canal.

When inserted into the deep regions of an ear canal, the conformal tip 100 creates an acoustic seal with the ear canal wall 170 thereby reducing acoustic feedback and occlusion effects. A gap 134 is formed on the proximal side of the contact area 132 and permits acoustic energy to easily migrate toward the outside environment and away from the tympanic membrane. Minimizing the area of contact between the conformal tip 100 and the ear canal wall 170 reduces discomfort to the user and allows the hearing device to be worn for longer periods of time.

The conformal tip 100 is preferably formed from a compressible foam. Foam materials are generally classified among other factors, by their recovery rate, i.e., the amount of time the foam material takes to completely return to its natural state after being compressed. The recovery rate of a conformal tip 100 constructed in accordance with the present invention is preferably less than 35 seconds. More preferably, the recovery rate of the conformal tip 100 is less than 20 seconds. Compression of the foam conformal tip makes it easier for a user to insert the device into an ear canal since when compressed, the size of the device is necessarily smaller, and can more easily fit into the ear canal. When the foam returns to its uncompressed shape, the contact area 132 engages with the ear canal wall and seals the device in the ear canal. The pressure exerted by the contact area 132 also acts as an anchor, securing the hearing device within the ear canal during its use.

In another preferred embodiment, the foam material includes a smooth skin 180 formed on its exterior surface (Best seen in Figs. 5 and 6). For ease of illustration, Figs. 5 and 6 show only a portion of the conformal tip 100 covered with the skin 180. Preferably, the entire conformal tip includes the skin 180. The skin 180 also allows easier insertion and removal of the hearing device and allows the device to be easily positioned at the most appropriate depth within the ear canal. Further, since the skin 180 is non-porous, it allows other materials to be applied to the outside of the conformal tip without being absorbed by the foam material. For example, antiseptics, cerumen repellants, and temporary adhesives can be applied to the skin 180.

Fig. 7 shows how a CIC hearing device receiver module 214 aligns with the conformal tip 100. Fig. 8 shows a complete CIC hearing device 210 that includes a receiver module 214 engaged within the conformal tip 100. The receiver module 214 preferably comprises a rigid shell 228 formed, e.g., from a plastic, thermoplastic or other polycarbonate material. The rigid shell (or housing) 228 provides a lightweight, durable, bio-compatible housing for the internal components of the receiver module 214, including a power source 236, a microphone 224, a receiver (not shown), a speaker 232, and sound processing electronics (not shown). Alternately, the receiver module 214 can be formed from a medical grade stainless steel or other bio-compatible and moisture resistant material. Notably, the housing 228 provides protection of the internal components from moisture, dirt, and oil from cerumen (ear wax).

The receiver module 214 further includes a removable faceplate 218 covering an open end 220 of the housing 228. The faceplate 218 allows access to the components

mounted inside of the receiver module 214. Located on the exterior of the faceplate 218 are controls 222 and a microphone 224. Briefly, the controls 222 provide the ability to adjust volume, sensitivity, or sound processing schemes. A door 226 is hinged to the receiver module 214 by a pin 216 and is also accessible from the exterior of the faceplate 218. Located behind the door 226 is a power source 236 preferably in the form of a standard size hearing device battery. The hinged door 226 swings outward (as indicated by arrow 227) and allows easy replacement of the battery 236. The distal end 231 of the receiver module 214 further includes a speaker 232, which operates in conjunction with the electronics (not shown) housed within the receiver module 214.

The chamber 142 of the conformal tip 100 is shaped to easily and snugly engage with the correspondingly shaped portion 230 of the receiver module 214. The chamber 142 is slightly smaller in size than the portion 230 of the receiver module 214 so that the receiver module is gripped and held in place by the conformal tip 100. The inside surface of the chamber 142 or the exterior surface of the portion 230 on the receiver module 214 can alternately be coated with a non-permanent adhesive to more securely attach the receiver module 214 to the conformal tip 100. Preferably, any such adhesive still allows the conformal tip 100 to be easily removed from the receiver module 214.

The conformal tip 100 of Fig. 8 includes a combined vent and retrieval cord 280. The channel 144 that extends through the sealing portion 120 and the retention portion 140 is adapted to receive a tubular device 280 that includes a lumen 288 extending therethrough. The lumen 288 is in communication with the channel 144. On the proximal end of the vent and retrieval cord 280 is a ridge or thickening 286 that facilitates grasping by a user and removal of the conformal tip 100 and receiver module 214. A retention and extraction device may also be incorporated into the conformal tip 100 of the present invention. U.S. Patent Application No. 09/409,793, filed on September 30, 1999, discloses and teaches a preferred embodiment of such a retention and extraction device, the details of which are hereby fully incorporated by reference into the present application.

Although the invention has been described and illustrated in the above description and drawings, it is understood that this description is by example only and that numerous changes and modifications can be made by those skilled in the art without departing from the true spirit and scope of the invention. The invention, therefore, is not to be restricted, except by the following claims and their equivalents.

What is Claimed is:

1. A conformal tip for a hearing aid, comprising:
a circumferentially enlarged sealing portion proximate a distal end of the
conformal tip, the sealing portion configured to form a seal with a wall of an ear canal.

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2. The conformal tip of claim 1, wherein the sealing portion is formed from a
compressible and self-recovering foam.

3. The conformal tip of claim 2, wherein the foam has a recovery rate of less than
10 35 seconds.

4. The conformal tip of claim 2, wherein the foam has a recover rate of less than
20 seconds.

15 5. The conformal tip of claim 1, further comprising a cavity on the distal end of
the conformal tip, wherein the cavity has an innermost surface including an aperture.

6. The conformal tip of claim 1, further comprising a vent aperture on the distal
end of the conformal tip.

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7. The conformal tip of claim 1, further comprising a narrowed region proximal to
the sealing portion, wherein the narrowed region has a lateral cross section smaller than
the lateral cross section of the sealing portion.

25 8. The conformal tip of claim 1, wherein the sealing portion has a substantially
oval lateral profile and the distal end of the sealing portion has a substantially bulbous
longitudinal profile.

9. The conformal tip of claim 1, further comprising a retention portion connected
30 to and distal to the sealing portion..

10. The conformal tip of claim 6, further comprising a channel in communication
with the vent aperture.

11. The conformal tip of claim 5, further comprising a membrane covering the cavity, wherein the membrane is transparent to acoustic energy and is repellant to cerumen.

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12. The conformal tip of claim 6, further comprising a membrane covering the vent aperture, wherein the membrane is transparent to acoustic energy and is repellant to cerumen.

10 13. The conformal tip of claim 2, wherein the foam has an external surface and includes a smooth skin covering at least a portion of the external surface.

14. The conformal tip of claim 1, further comprising a combined vent and retrieval cord.

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15. A conformal tip for a hearing aid comprising:
a circumferentially enlarged sealing portion proximate a distal end of the conformal tip, the sealing portion configured to form a seal with a wall of an ear canal; and
20 a retention portion attached to a proximate end of the sealing portion and adapted to receive a hearing device.

16. The conformal tip of claim 15, wherein the sealing portion has a lateral cross section that is larger than the lateral cross section of the retention portion.

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17. The conformal tip of claim 15, wherein the sealing portion and the retention portion are formed from a compressible and self-recovering foam.

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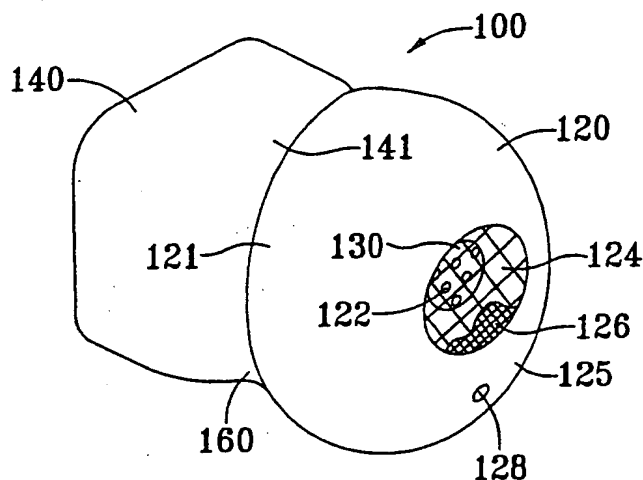


FIG. 1

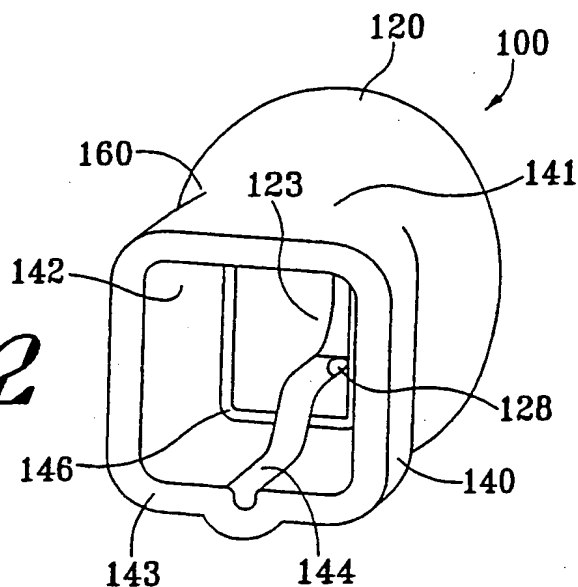


FIG. 2

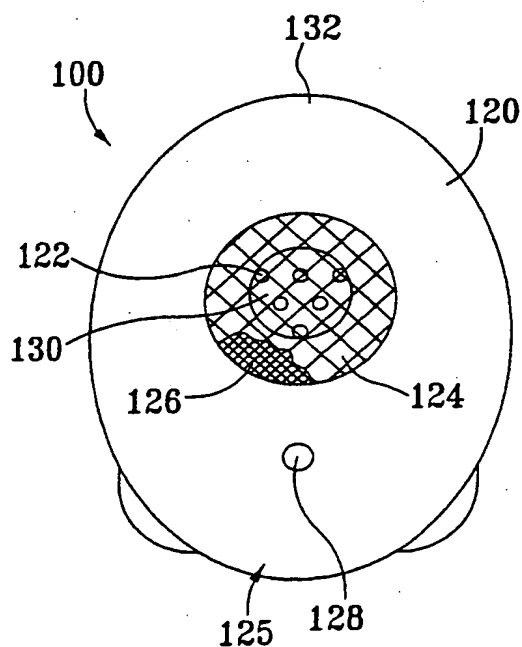


FIG. 3

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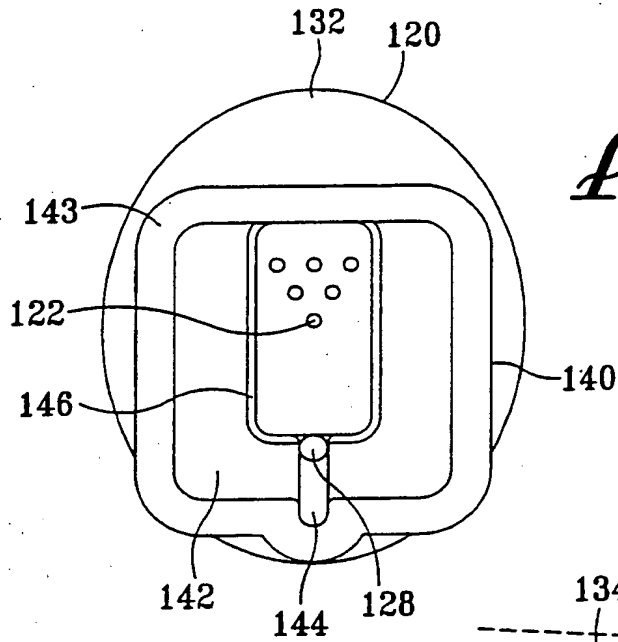


FIG. 4

FIG. 5

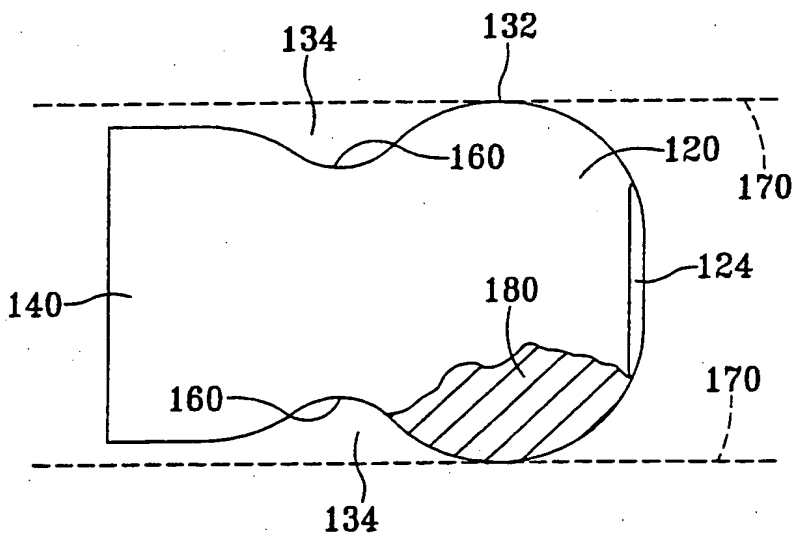
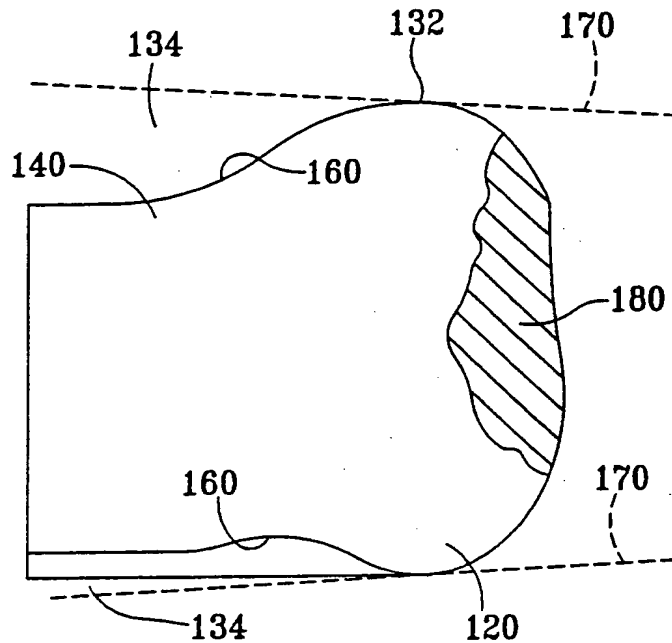
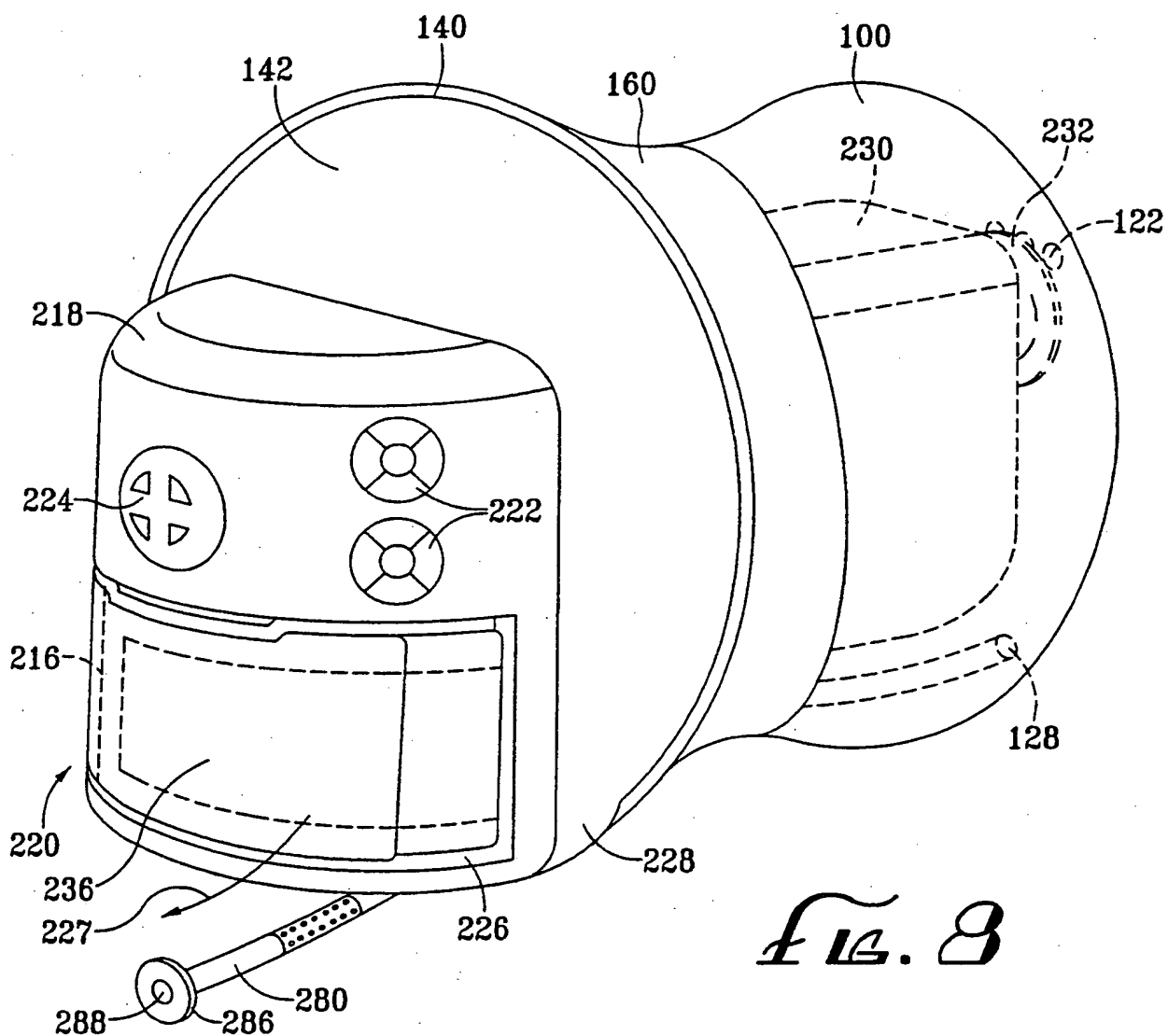


FIG. 6

*FIG. 8*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/33192

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :H04R 25/00

US CL :381/325, 328, 380; 181/135.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 381/322, 325, 328, 329, 330 380, FOR 133; 181/128, 129, 135.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,878,560 A (SCOTT) 07 November 1989, figures 2-3.	1-10, 13, 15 and 17
X	US 5,701,348 A (SHENNIB et al.) 23 December 1997, figures 3, 10-11, 18 and 30	1-10 and 1-16.
X	US 4,987,597 A (HAERTL) 22 January 1991, figures 4, 8, 12 and 16.	1, 5-6 and 11-12.
X	US 5,395,168 A (LEENEN) 07 March 1995, figures 1-2	1 and 14
X	US 5,920,636 A (OLIVEIRA et al.) 06 July 1999, figures 2 and 4.	1-2 , 5, 11 and 15-16

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

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P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Z document member of the same patent family

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